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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/826,791	04/05/2001	Lee Harland	PCS10914ADAM	4080

7590 11/15/2001

Gregg C. Benson
Pfizer Inc.
Patent Department, MS 4159, Eastern Point Road
Groton, CT 06340

EXAMINER	
CHERNYSHEV, OLGA N	
ART UNIT	PAPER NUMBER
1646	4

DATE MAILED: 11/15/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/826,791	HARLAND, LEE	
	Examiner	Art Unit	
	Olga N. Chernyshev	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-22* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6 and 22, drawn to polynucleotide of SEQ ID NO:1, vector, host cell and process for protein production, classified in class 435, subclass 69.1, for example.

II. Claims 1-6 and 22, drawn to polynucleotide of SEQ ID NO:5, vector, host cell and process for protein production, classified in class 435, subclass 69.1, for example.

III. Claim s 7-8, drawn to a polypeptide of SEQ ID NO:2, classified in class 530, subclass 350, fro example.

IV. Claims 7-8, drawn to a polypeptide of SEQ ID NO:6, classified in class 530, subclass 350, for example.

V. Claims 9-11, drawn to antibody to the polypeptide of SEQ ID NO:2, classified in class 530, subclass 387.1, fro example.

VI. Claims 9-11, drawn to antibody to the polypeptide of SEQ ID NO:6, classified in class 530, subclass 387.1, fro example.

VII. Claims 10, 12, drawn to a compound which modulates the activity of the polypeptide of SEQ ID NO:2, classified in class undetermined, subclass undetermined, for example.

IIX. Claims 10, 12, drawn to a compound which modulates the activity of the polypeptide of SEQ ID NO:6, classified in class undetermined, subclass undetermined, for example.

IX. Claims 13, 15-16, drawn to a method of treatment using an antibody to the polypeptide of SEQ ID NO:2, classified in class 424, subclass 130.1, fro example.

X. Claims13, 15-16, drawn to a method of treatment using an antibody to the polypeptide of SEQ ID NO:6, classified in class 424, subclass 130.1, for example.

XI. Claims 14-17, drawn to a method of treatment using a compound which modulates the polypeptide of SEQ ID NO:2, classified in class 514, subclass 2, fro example.

XII. Claims 14-17, drawn to a method of treatment using a compound which modulates the polypeptide of SEQ ID NO:6, classified in class 514, subclass 2, fro example.

XIII. Claim 18, drawn to a genetically modified cell expressing the protein of SEQ ID NO:2, classified in class 435, subclass 326, for example.

XIV. Claim 18, drawn to a genetically modified cell expressing the protein of SEQ ID NO:6, classified in class 435, subclass 326, for example.

XV. Claims 19-21, drawn to a method for identifying a compound using the polypeptide of SEQ ID NO:2, classified in class undetermined, subclass undetermined, for example.

XVI. Claims 19-21, drawn to a method for identifying a compound using the polypeptide of SEQ ID NO:6, classified in class undetermined, subclass undetermined, for example.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions (I, III, V, VII, IX, XI, XIII and XV) and (II, IV, VI, IIX, X, XII, XIV and XVI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions case the different inventions are not required one for the other in that the polynucleotide of SEQ ID NO:1 and the polypeptide of SEQ ID NO:2 as well as products and methods involving these polynucleotide and polypeptide are not required for the polynucleotide of SEQ ID NO:5 or the polypeptide of SEQ ID NO:6 and products and methods involving them.

3. Inventions (I, II) and (III, IV) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of Groups I and II and polypeptides of Groups III and IV are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for the processes other than the production of the protein, such as nucleic acid hybridization assay.

4. Inventions (III, IV) and (V, VI) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Groups III and IV and antibodies of Groups V and VI are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used in another and entirely different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify the natural ligand of the protein.

5. Inventions (I, II) and (V, VI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Further, antibodies of Groups V and VI can also be used in materially different methods, such as in various diagnostic (e.g. as a probe in immunoassays or immunochromatography), or therapeutic methods.

6. Inventions ((IX, X), (XI, XII) and (XV, XVI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to different methods that recite structurally and functionally distinct elements, are not required one for the other, achieve different goals, and therefore constitute patentably distinct inventions.

7. Inventions (I, II) and (VII, IIX), (IX, X), (XI, XII), (XV, XVI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the polynucleotides of Groups I-II are not required for the inventions of Groups (VII, IIX), (IX, X), (XI, XII), (XV, XVI).

8. Inventions (I, II) and (XIII, XIV) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of Groups I and II could be used in an entirely different manner such as for the production of proteins rather than in the inventions of Groups (XII, XIV).

9. Inventions (III, IV) and (IX, X), (XIII, XIV), (XV, XVI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the polypeptides of Groups III and IV are not required for the inventions of Groups (IX, X), (XIII, XIV), (XV, XVI).

10. Inventions (III, IV) and (VII, IIX), (XI, XII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Groups III and IV could be used in an entirely different manner such as for the production of antibodies rather than in the inventions of Groups (VII, IIX), (XI, XII).

11. Inventions (V, VI) and (VII, IIX), (XI, XII), (XIII, XIV), (XV, XVI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the antibodies of Groups V and VI are not required for the inventions of Groups (VII, IIX), (XI, XII), (XIII, XIV), (XV, XVI).

12. Inventions (V, VI) and (IX, X) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of Groups V and VI could be used in an entirely different manner such as for the method of purification of proteins rather than in the methods of Groups IX and X.

13. Inventions (VII-XII and XV-XVI) and (XII, XIV) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the

genetically modified animal cells of Groups XIII and XIV are not required for the inventions of Groups (VII-XII and XV-XVI).

14. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter and non-coextensive literature searches, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-0294 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December

28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D. OC
November 8, 2001

CHRISTINE J. SAOUD
PRIMARY EXAMINER
Christine J Saoud